REMARKS

In response to the Office Action mailed July 9, 2009 ("the Office Action"), Applicants respectfully request reconsideration and reexamination of this application, removal of the rejections outlined below, and the timely allowance of the pending claims.

Status of the Claims

Claims 40-41, 43, 50-59, and 63-67 were under consideration in this application. Claims 44-49 were previously withdrawn. By this Amendment, Applicants have canceled claims 57 and 58 and amended claims 40, 52, 59, 63, and 67. Accordingly, claims 40-41, 43, 50-56, 59, and 63-67 are currently being examined.

Objection to the Claims

The Examiner has objected to claim 52 as having insufficient antecedent basis for "the contrast agent." Office Action at p. 4. Claim 52 is amended above to replace "agent" with "medium," to clarify that claim 50's "a contrast medium" provides antecedent basis for the language at issue. Applicants submit that the outstanding objection is rendered moot in light of this amendment, and respectfully request that it be withdrawn.

Rejection Under 35 U.S.C. § 112

Claim 64 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled by the disclosure. *Id.* at p. 4. The Examiner asserts, "Where 'the tissue

engager does not extend distally beyond the tissue piercing tip' is critical or essential to the practice of the invention, but not included in the claims(s) is [sic] not enabled by the disclosure." Applicants respectfully traverse this rejection and the Examiner's characterizations of claim 64 and the specification.

"As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims." M.P.E.P. § 2164.08. Here, claim 64 recites: "The kit of claim 40, further comprising a tool, the tool comprising a tissue engager and a tissue cutter, wherein the tissue engager can move relative to the tissue cutter, and wherein the tissue engager does not extend distally beyond the tissue piercing distal tip." Support for the scope of the portion of claim 64 singled out by the Examiner may be found at least in Figs. 10-14 and paragraphs [0067] and [0068] (as numbered in US Publication No. 2006/0036272, which corresponds to the present application), all of which were included in the present application's parent, International Application No. PCT/US2005/027216. For example, Fig. 12 illustrates an exemplary tissue engager 64 that, when fully deployed, does not extend distally beyond the tissue piercing distal tip of the tool. Accordingly, Applicants respectfully request that the outstanding rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejection Under 35 U.S.C. § 102(b)

Claims 40-41, 43, and 63-67 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,954,739 to Bonutti ("Bonutti"). Office Action at p. 5.

Applicants traverse the section 102(b) rejection of claims 40-41, 43, and 63-67 and respectfully request withdrawal of the rejections for at least the following reasons.

To anticipate a claim, "[t]he identical invention must be shown in as complete detail as is contained in the... claim." *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236 (Fed. Cir. 1989); *see* § MPEP 2131. Claim 40, as currently amended, recites the following (emphasis added):

> 40. A kit for performing a procedure on a spine, the spine including an epidural space containing a thecal sac, the kit comprising:
>
> an insertion member for accessing the epidural space, the insertion member comprising a tissue piercing distal tip; and
>
> a non-inflatable mechanical shield sized and shaped to be inserted into the epidural space by the insertion member and configured to be mechanically extended so as to protect and displace a portion of the thecal sac and provide a safety zone within the epidural space.

At least because Bonutti discloses neither "a non-inflatable mechanical shield[,]" nor a mechanical shield "sized and shaped to be inserted into the epidural space... and configured to be mechanically extended so as to protect and displace a portion of the thecal sac[,]" Bonutti cannot anticipate claim 40.

First, claim 40, as amended, recites "a non-inflatable mechanical shield[,]" but Bonutti only discloses the use of inflatable structures. Bonutti's invention is a "fluid operated retractor" with an expandable portion that "is inflated to enough pressure[] to spread adjoining tissues within the body." Bonutti at Abstract. Accordingly, Bonutti describes numerous embodiments of retractors that utilize inflatable balloons or bladders to retract tissue, and emphasizes the advantages of using an inflatable structure over mechanical structures used in the past. *See id.* at col. 2, ll. 3-15, col. 7, ll.

49-51 and 65-67, col. 8, ll. 9-11. However, nowhere does Bonutti disclose "a non-inflatable mechanical shield" as claimed, and thus, Bonutti cannot anticipate claim 40.

Second, the limitations "sized and shaped to be inserted into the epidural space" and "configured to be mechanically extended so as to protect and displace a portion of the thecal sac" are structural limitations that differentiate the claimed kit from Bonutti, and Applicants respectfully traverse the Examiner's contentions to the contrary. *See* Office Action at p. 10. While, in some circumstances, the manner in which a claimed apparatus is intended to be used may not alone differentiate the claimed apparatus from a prior art apparatus, *see e.g.*, M.P.E.P. § 2114, in other circumstances a claimed element may be "as well defined by its intended use as by its dimensions or other physical characteristics[.]" *In re Benson*, 164 USPQ 22, 25 (C.C.P.A. 1969). In particular, where claim language identifies a function that the invention, or an element thereof, must be capable of performing, it is structurally limiting and if the prior art lacks the capability, it can distinguish the claim over the prior art. *See id.*; *see also Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989)(finding the phrase "[a]n optical waveguide[,]" included in the claim preamble, constituted a positive limitation of the claimed invention, and distinguished the claim over prior art that disclosed a device that could not be used as an optical waveguide). For example, in *In re Benson*, the Court of Customs and Patent Appeals, a predecessor court of the Federal Circuit, found that the language "for frictional centering engagement within a machine element bore[,]" describing an external surface of a shell in claims for a clutch apparatus, should be interpreted as a meaningful limitation on the claimed external surface. *In re Benson*, 164 USPQ at 25. There, the court found the claims

distinguishable from shells disclosed in the prior art, as the prior art shells were described as "hard" or "stiffened," and thus, lacking the expansion property needed need to allow for the claimed frictional engagement. *Id.* at 25.

In the present case, the claims include language that, like the language in *In re Benson*, defines structure by functions that the structure must be capable of accomplishing. Specifically, the claims recite a mechanical shield that is "sized and shaped to be inserted into the epidural space" and "configured to be mechanically extended so as to protect and displace a portion of the thecal sac[.]" Accordingly, as in *In re Benson*, this language should be interpreted as meaningful limitations and as capable of distinguishing the claims over prior art that does not disclose structures capable of such functions.

As discussed in Applicants' Response to the last Office Action, nowhere does Bonutti disclose, teach, or suggest a device "sized and shaped to be inserted into the epidural space... and configured to be mechanically extended so as to protect and displace a portion of the thecal sac[.]"

Bonutti provides a tissue retractor for spreading a bone joint or dissecting tissue layers. *See* Bonutti at Abstract. Bonutti explicitly states that prior art devices were not "powerful enough" or "made of material which is strong and resilient enough to, for example, separate tissue planes from within." *Id.* at col. 1, ll. 47-50. Joints and connective tissue require large forces to separate adjacent structures, and traditional inflatable devices "do not have anywhere near the strength, or the ability to hold enough fluid pressure, or shapes to retract tissue as described herein." *Id.* at col. 2, ll. 43-45.

To accommodate these greater pressures, the devices of Bonutti are made of Kevlar or Mylar, and may be reinforced with steel, nylon, or other fibers. *Id.* at col. 2, ll. 46-51.

In contrast to Bonutti, the present application is directed to epidural structures, such as, for example, the thecal sac and ligamentum flavum. *See* Current Application at para. [0046], [0047], Figs. 1, 2. Because the thecal sac is mostly water, it is highly compressible. *Id.* at para. [0047]. As such, any displacement or compression of the thecal sac should be performed gently. *Id.* at para. [0048].

The Examiner alleges that Bonutti discloses "an expandable device (64) adapted to be inserted into the epidural space (col. 3, lines 56-58)...." Office Action at p. 3. However, at column 3, lines 56-60, Bonutti merely states that an alternate "use for the retractor of the present invention is to operate in a joint of the spine, and specifically between two vertebrae. The retractor is used to spread two vertebrae apart to enable removal of the spinal disc from between the vertebrae." (emphasis added) This simply reiterates that the invention of Bonutti is a retractor that is specifically designed to withstand high forces for separating joints. Furthermore, this large scale of size and force, as compared to that of epidural structures, dictates that Bonutti's device would be incapable of the precise control needed for gentle displacement of the highly compressible thecal sac in the epidural space. Consequently, Bonutti fails to disclose, teach, or suggest a device "sized and shaped to be inserted into the epidural space by the insertion member and configured to be mechanically extended so as to protect and displace a portion of the thecal sac[,]" as claimed, and thus, cannot anticipate claim 40.

Claims 41, 43, and 63-67 ultimately depend from claim 40, and are therefore not anticipated by Bonutti for at least the reasons discussed above regarding claim 40.

Rejection Under 35 U.S.C. § 103(a)

Claims 50-52, 57, and 58 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bonutti in view of U.S. Patent No. 5,429,139 to Milo et al. ("Milo"). Office Action at p. 7. Claims 53-56 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bonutti in view of U.S. Patent No. 7,329,402 to Unger et al. ("Unger"). *Id.* at p. 8. Claim 59 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Bonutti in view of U.S. Patent No. 5,985,320 to Edwards et al. ("Edwards"). *Id.* at p. 9. Applicants traverse these section 103(a) rejections and respectfully request withdrawal of the rejections for at least the following reasons.

Claims 50-59 ultimately depend from claim 40. Thus, at least because Bonutti fails to disclose, teach, or suggest "a non-inflatable mechanical shield sized and shaped to be inserted into the epidural space... and configured to be mechanically extended so as to protect and displace a portion of the thecal sac[,]" as claimed, and discussed above, dependent claims 50-59 are not unpatentable over Bonutti. Further, Milo, Unger, and Edwards do not cure the deficiencies of Bonutti discussed above. Therefore, Applicants respectfully request that the Examiner withdraw the rejection of claims 50-59 under 35 U.S.C. § 103(a) for at least the same reasons as above for claim 40. Applicants need not and do not address the Examiner's additional contentions with respect to Milo, Unger, and Edwards and certain elements of certain claims. By not addressing those contentions, Applicants in no way acquiesce to them.

Conclusion

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

In discussing the claims in this Response, it is to be understood that Applicants are in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification, abstract, or shown in the drawings. Rather, Applicants are entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

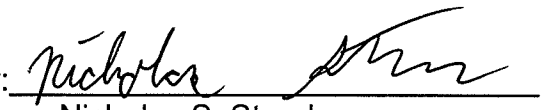
In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

If there is any fee due in connection with the filing of this Preliminary Amendment, please charge the fee to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: January 7, 2010

By: 

Nicholas S. Stroeher
Reg. No. 62,926
(617) 452-1647